

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 07/29/96 OUT 08/01/96

Reviewed by Srinivas Gowda Date 08/01/96
Z. Vaituzis
 LAN Code 10492-4
 EPA Reg. No. or File Symbol 10492-4.607
 EPA Petition or EUP No. None
 Date Division Received 07-26-96
 Type Product Pre-Saturated Towelettes
 MRID No (s) None
 Product Manager PM-31 Johnson/Terry
 Product Name DisCide Disinfecting Towelette
 Company Name Palmero Health Care
 Submission Review and Evaluation of Proposed Test Protocol For
Evaluating Pre-Saturated Towelettes for Hard Surface
Disinfection against Mycobacterium bovis - Single Use
 Type Formulation Single-Use Pre-Saturated Towelettes
Active Ingredient (s): %
Quaternary ammonium and Isopropanol.....Unspecified

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages 4

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GENERAL SERVICES ADMINISTRATION

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202.0 Recommendations

202.1 Evaluation of Pre-Saturated Towelettes for Hard Surface Disinfection - Single Use Against Mycobacterium bovis BCG Protocol

202.2 Comments

The submitted proposed protocol is suitable for meeting the criteria specified in the EPA product performance guidelines for the determination of the tuberculocidal activity of pre-saturated towelettes against Mycobacterium bovis on inanimate, hard, non-porous surfaces. However, the following revisions or additions should be made to the protocol:

1. On page 4 of 6, under the heading "Subculture":
 - (a) In the first paragraph, to the sentence "Each carrier is then aseptically transferred to Modified Proskauer-Beck medium" add "and shaken/mixed/vortexed" or the like.
 - (b) In the first paragraph, revise the third sentence to read: "Without undue delay, from each bottle containing the neutralizer, 1 ml and 0.1 ml aliquots of neutralizer solution will be transferred to a tube of Middlebrook 7H9 broth and a tube of Kirchner's broth." (The neutralization confirmation should be done at this step using 1 ml and 0.1 ml aliquots described above)
 - (c) In the second paragraph, revise the statement following "Liquid expressed from the used towelette will be transferred to a bottle containing 10 ml of the neutralizer" to read "...and mixed. Immediately following this step, from each bottle containing the neutralizer, 1 ml and 0.1 ml aliquots of neutralizer solution will be transferred to a tube of Middlebrook 7H9 broth and a tube of Kirchner's broth."
2. On page 3 of 6, specify the ATCC number of Mycobacterium bovis BCG.
3. Ten carriers must be tested against Mycobacterium bovis (BCG) with each of 2 samples, representing 2 different batches (10 carriers per sample; a total 20 carriers).
4. Under the heading "Culture Preparation" include procedure to incorporate 5% blood serum in to the inoculum to simulate the intended use situation (since in the environment M.tb. is encased in sputum and/or blood). (Note: this is not to be understood as a "one-step" disinfection requirement).

(continued)

5. For volatile products (e.g. alcohol), to simulate the intended use situation, do not expose contaminated slides to chemicals in closed petri dishes. Therefore, under the heading "Medication" include the statement "After wiping the contaminated glass slide carrier with the saturated towelette hold the slide for the required contact time in petri dish without its cover in an open air environment."
6. Carrier quantitation control results will be reported with other control results in the final report.
7. All tubes/flasks will be incubated under aerated conditions (loose screw-caps may be used). The conditions used to ensure aeration throughout the 60 day incubation period will be described in the final report.